

identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 26, 1996.

William K. Hubbard,
Associate Commissioner for Policy
Coordination.

[FR Doc. 96-33382 Filed 12-31-96; 8:45 am]

BILLING CODE 4160-01-F

Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HF (Food and Drug Administration) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, and 56 FR 29484, June 27, 1991, as amended most recently in pertinent part at 60 FR 65350, December 19, 1995) is amended to reflect the realignment of the Office of Surveillance and Biometrics, Center for Devices and Radiological Health (CDRH), Office of Operations, in the Food and Drug Administration (FDA).

The functional statements of the Office of Surveillance and Biometrics have been modified to include participation in research and consultation on health economics and cost effectiveness methodology issues. In addition, program management activities have been elevated to the immediate office which will tighten the span of control within the Office.

Under section HF-B, Organization:

1. Delete the subparagraph *Program Management Staff (HFWH2)*, *Center for Devices and Radiological Health (HFW)*, in its entirety.

2. Delete the subparagraphs *Office of Surveillance and Biometrics (HFWH)* in their entirety and insert the following new subparagraphs under *Office of Surveillance and Biometrics (HFWH)*, reading as follows:

Office of Surveillance and Biometrics. Advises, coordinates, and provides consultation to the Center Director and other Agency officials including the Commissioner on Center programs and policies concerning premarket review activities, postmarket management activities, surveillance and biometrics programs and activities, and regulatory matters for medical devices and radiological products.

Establishes policy for surveillance programs. Designs, develops, and implements a Center program to acquire device experience information; identifies and analyzes device problems; develops solution strategies to such

problems; and tracks programs or solution implementations.

Provides statistical, epidemiological, and biometric services, and conducts research in support of the operating and scientific programs of the Center.

Represents the Center with other governmental agencies (Federal, State, and International), industry, and consumer organizations on issues related to the activities of the Office including postmarket management activities.

Provides consultation to Center Offices on health economics and cost effectiveness methodology issues pertaining to claims for medical devices.

Plans, develops, and implements office administrative support and services including program planning, financial management, extramural and collaborative efforts, procurement, travel, personnel administration, employee development and training, employee evaluations, recognition programs, property management, and facility space management.

3. Delete the subparagraphs *Issues Management Staff (HFWH1)* in their entirety and insert the following new subparagraphs under paragraph *Issues Management Staff (HFWH1)*, *Center for Devices and Radiological Health (HFW)*, reading as follows:

Issues Management Staff (HFWH1). Directs and monitors the analysis, resolution, development and solution implementation of postmarket issues; presents these issues to the CDRH, FDA, other agencies, and foreign governments as appropriate. Coordinates and disseminates information on developing issues and solution strategies within CDRH, FDA, and with other agencies and foreign governments as appropriate.

Provides and coordinates input on postmarket concerns and perspectives in support of Center initiatives, including encouragement and facilitation of the use of postmarket data available within the Center.

Develops and directs systems that track and monitor CDRH's postmarket surveillance issues; documents the recommendations, resolutions, and solution monitoring, and produces final reports for review by Center management.

Directs the preparation of issue papers and other reports or studies to promote the resolution of public health issues; coordinates these analyses with subject matter experts throughout CDRH, FDA and other Department of Health and Human Services agencies as required.

Represents CDRH's postmarketing surveillance concerns at industry, trade, professional, Agency, and international meetings. Develops and delivers

speeches and papers, and acts as the Center's liaisons for postmarket issues.

4. Prior Delegations of Authority. Pending further delegations, directives, or orders by the Commissioner of Food and Drugs, all delegations of authority to positions of the affected organizations in effect prior to this date shall continue in effect in them or their successors.

Dated: November 27, 1996.

Michael A. Friedman,
Deputy Commissioner for Operations.

[FR Doc. 96-33383 Filed 12-31-96; 8:45 am]

BILLING CODE 4160-01-F

Substance Abuse and Mental Health Services Administration

Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given of the following meeting of the SAMHSA Special Emphasis Panel I in January.

A summary of the meeting and a roster of the members may be obtained from: Ms. Dee Herman, Committee Management Liaison, SAMHSA Office of Extramural Activities Review, 5600 Fishers Lane, Room 17-89, Rockville, Maryland 20857. Telephone: (301)443-4783.

Substantive program information may be obtained from the individual named as Contact for the meeting listed below.

The meeting will include the review, discussion and evaluation of individual grant applications. These discussions could reveal personal information concerning individuals associated with the applications. Accordingly, this meeting is concerned with matters exempt from mandatory disclosure in Title 5 U.S.C. 552b(c)(6) and 5 U.S.C. App.2, Section 10(d).

Committee Name: SAMHSA Special Emphasis Panel I (SEP I).

Meeting Date: January 9, 1997, 9:00 a.m.-12:00 Noon.

Place: Doubletree Hotel—Room: Presidential II, 1750 Rockville Pike, Rockville, Maryland.

Closed: January 9, 1997, 9:00 a.m. until 12:00 Noon.

Panel: Cooperative Agreement with the National Association of State Alcohol and Drug Directors (NASADAD) GFA No. AS 97-0001.

Contact: Katie Baas, Room 17-89, Parklawn Building, Telephone: (301) 443-2592 and FAX: (301) 443-3437.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.